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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,346	04/15/2005	Stefan Frahling	GIL-16027	8225
7609 7590 04/29/2009 RANKIN, HILL & CLARK LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/531,346

**Applicant(s)**

FRAHLING ET AL.

**Examiner**

Jeffrey T. Palenik

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,10 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,10 and 15-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

Receipt is acknowledged of Applicants' Request for Continued Examination (RCE), Amendments ("E") and Remarks filed 5 February 2009. Said remarks and amendments are entered on the record. Receipt of Applicants' Supplemental Response and Amendments (Amendment "F"), filed 18 February 2009 is also acknowledged and is hereby entered on the record. The Examiner further acknowledges the following:

Claims 1, 4-6, 10 and 15-22 have all been amended. The term "scaffold-forming" has been replaced with "skeleton-forming" in claims 1, 4 and 5. The phrase "and/or" has been removed from claims 10, 17 and 21. The remaining claims have been amended for clarity. Support for the amendments, while not expressly provided, were found either within Applicants' disclosure and/or originally filed claims.

No claims have been added.

Claims 2, 3, 7-9 and 11-14 have been cancelled.

No new matter has been added.

As such, claims 1, 4-6, 10 and 15-22 continue represent all claims currently under consideration.

#### **INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statement (IDS) have been submitted for consideration.

**WITHDRAWN OBJECTIONS/REJECTIONS**

Objection to the Specification

Applicants' amendments to claims 1, 4 and 5 regarding the removal of the phrase "scaffold-forming agent" render the objection to the Specification moot. Thus, said objection has been **withdrawn**.

Objection to the Claims

Applicants' amendment to claim 1, renders the objections to claims 10, 15, 16, 21 and 22, moot. Thus, said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicants' amendment to claim 10, as discussed above, renders the rejection under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

Rejection under 35 USC 103(a)

Applicants' remarks to claim 1, particularly those directed to the lack of motivation for increasing the size (e.g. diameter) of the microparticles taught by Nagashima (USPN 6,296,817), render moot the rejection to claims 1, 4-6, 10 and 15-22 under 35 USC 103(a) as being unpatentable over Nagashima. Thus, said rejection has been **withdrawn**.

#### **NEW REJECTIONS**

In light of Applicants' remarks, most notably to claim 1, the following rejection have been newly added:

#### **CLAIM REJECTIONS - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 15, 16, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Within the rejected claims 10, 15, 16, 21 and 22, Applicants refer to the "aqueous solution" as further comprising active substances (e.g. cosmetically active or pharmaceutically active substances), as well as auxiliary substances. Claim 16 recites broad categories of compounds which do further limit the category of "auxiliary substances". Though each of the aforementioned categories is extremely well known in the art, the claims are nevertheless rendered indefinite because it is not clear either from the instant claims, Applicants examples or the remainder of the instant disclosure, what Applicants are claiming as their instant invention. Thus, for the purposes of examination on the merits and despite the amendment to claim 1, the Examiner continues to interpret the limitations of an "aqueous solution" comprising "pharmaceutically active", "cosmetically active", or "auxiliary" substances as recited in claims 10, 15, 16, 21 and 22, as broadly as water (e.g. tap water).

**CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6, 10 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kojima (US Pre-Grant Publication N° 2002/0068683).

The instant claim 1 is directed to a method of using a shaped article to apply at least one skeleton-forming agent to an external skin or hair surface of a human or animal comprising (1)

providing a sized and shaped article, free of protein-based scaffolding agent, (2) disintegrate said article with an aqueous solution to form a solution or a gel, and (3) applying the composition to the intended surface. With regard to the limitations recited in claim 1, which state that the shaped article has been “molded [and] freeze-dried”; said limitations are deemed by the Examiner as reciting product-by-process limitations, which per MPEP §2113 hold no patentable weight. Said shaped article is further claimed as having a volume ranging from 100 microliters to 6 mL and a diameter ranging from 3-60 mm. The skeleton-forming agent recited in claim 1, is further recited as comprising at least one polysaccharide such as sodium alginate (claims 4 and 5). Claim 6 recites the article as sphere-shaped prior to contact with water (claim 6). The limitation recited within the amended claim 10, states that “the shaped article is contacted with an aqueous solution comprising one selected from the group consisting of active substances or auxiliary substances”. Claim 15 further limits the “active substance” to either a “cosmetic active substance” or a pharmaceutical active substance. Claim 16 further limits the auxiliary substance to compounds such as pH-adjusting agents, buffering substances, plasticizers and lubricants. Claims 21 and 22, which depend from claims 17 and 21 respectively, recite the same limitations as claims 10 and 15, respectively. Herein, and for the purposes of examination on the merits, despite the amendment to claim 1, the Examiner continues to interpret the recitation of an “aqueous solution” in claims 10, 15, 16, 21 and 22, as “contacting the shaped article with water (e.g. tap water)”. The shaped article is recited as further comprising one or more cosmetic or pharmaceutically active substances (claims 17 and 18) or one or more auxiliary substances such as squalane (claims 17-20).

The Abstract to Kojima teaches a shaped, water-soluble solid composition that produces a lubricating liquid when dissolved in water. The composition is also hand-held, able to be moistened and then applied to dry skin as a liquefied lubricant. The instantly claimed shape limitations are taught, such that the composition may be sphere-shaped (see Abstract and Fig. 6F) as well as varied in size or dimension. Test Examples 1 and 2, for instance, teach the composition as being compressed and molded from a 30-mm cube into a shape (e.g. column) having a 12-mm diameter. Based on this teaching, a molded sphere, having a 12-mm diameter an approximate volume of 905 microliters (i.e.  $V_{sp} = (4/3)\pi r^3$ ) is conceivable, thereby teaching the limitations of the instant claims 1 and 6. The limitations of claims 4 and 5 are taught such that the composition comprises a “solidifying agent” (claim 4), which is further defined as comprising sodium alginate ¶[0018]. The limitations of claims 17-20 are taught, such that the composition may contain one or more auxiliary substances or additives (Abstract; claim 1, and ¶[0024] and [0038]) as well as active substances such as antiseptics ¶[0024]. Paragraph [0039] teaches the use of additives such as squalane. The limitations of claims 10, 15, 16, 21 and 22 are taught such that the solid, shaped composition is contacted with an aqueous solution such as water prior to or concurrent with application of the composition to the skin.

All claims have been rejected; no claims are allowed.

#### CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966.



The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615